# Proof-of-principle study of steam ablation as novel thermal therapy for saphenous varicose veins

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***Introduction:*** **During the last decade, thermal ablation techniques such as endovenous laser ablation have been challenging the position of traditional surgery for the treatment of saphenous varicose veins. The newest method of thermal ablation is pulsated steam, which works by heating the vein with steam at 120°C. This study assessed the effectiveness of steam ablation of varicose veins in sheep and in humans.**

***Methods:*** **The safety of the procedure in sheep was assessed by cardiovascular monitoring during treatment. We used ultrasound imaging to examine occlusion of the veins. Changes in treated veins were examined microscopically. In a pilot study, 20 veins in 19 patients with insufficiency of the great or the small saphenous vein were treated with pulsated steam ablation. Anatomic success, patient satisfaction, and complications were investigated for 6 months after the procedure.**

***Results:*** **All veins in the sheep were occluded. No cardiovascular changes occurred during treatment. Histologic examination of treated veins showed typical changes of the vein wall, such as disappearance of the endothelial layer, fibrotic thrombosis, and major alterations in collagen fibers in the media. Steam ablation was effective in the 19 patients: 13 of 20 veins were completely closed, and 7 showed a very small segment of recanalization after 6 months of follow-up that did not seem to be clinically relevant. Nine patients had some ecchymoses at the puncture site, and one patient had a transient superficial phlebitis. A median maximal pain score of 1 (range, 0-10) was reported. No serious side effects, such as deep vein thrombosis, nerve injury, skin burns, or infections, were reported. Patients were very satisfied with the treatment, with a median satisfaction score of 9.25 (range, 0-10).**

***Conclusions:*** **In this proof-of-principle study, pulsated steam ablation was an effective treatment for saphenous varicose veins. (J Vasc Surg 2011;53:181-6.)**

***Clinical Relevance:*** **This article describes a proof-of-principle study on the newest thermal endovascular treatment, steam ablation. It describes the first group of patients treated with hyperheated steam of 120°C for ablation of saphenous varicose veins. It also reports basic experimental data of this treatment on sheep to investigate the safety profile and the morphologic and histologic changes resulting from steam ablation. Steam ablation in the patients was effective, safe, and very well appreciated by the patients. This article describes the steam ablation procedure in humans, shows the first results, and provides basic background information received from animal experiments.**

For more than a century, saphenous varicose veins have been treated surgically with ligation and stripping of the saphenous veins. During the last decade, however, minimally invasive therapies for treating saphenous veins have been replacing traditional surgery, because they produce a lower recurrence rate, higher health-related quality of life, higher treatment satisfaction, and a lower complication rate.[1] A comparative meta-analysis of four different therapies showed that endovenous laser ablation (EVLA) was superior, followed by nonsegmental radiofrequency ablation (RFA), ultrasound (US)-guided foam sclerotherapy, and stripping, with success rates of 95%, 80%, 74%, and 76%, respectively, after 5 years of follow-up.[2]

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The mechanism of ablation in endovenous thermal therapies such as EVLA and RFA is based on heating the venous structure, and in EVLA, creating intravascular "steam bubbles."[3] The rise in temperature during EVLA is very high, inducing blood carbonization, evaporation of the laser fiber tip, and perforation of the venous wall.[4] Patients also report the taste of burned blood during EVLA. These observations hypothesize that foreign material may stay within the body and justify our search for other treatment modalities.

Steam ablation is a new method of thermal vein ablation. Its objective is to achieve a safer and easier method of thermal ablation that has fewer side effects. No studies have reported on steam ablation yet. The present article describes a proof-of-principle study in which we assessed the effectiveness and safety of steam ablation in animal experiments and in a pilot study involving 19 patients with varicose veins. The purpose of our studies was to assess safety and effectiveness of steam ablation, first in animals and then in patients, in a proof-of-principle study and to investigate patient satisfaction of the steam treatment.

## MATERIALS AND METHODS

For the steam ablation, the Steam Vein Sclerosis (SVS) system (CERMA SA, Archamps France) was used. The SVS

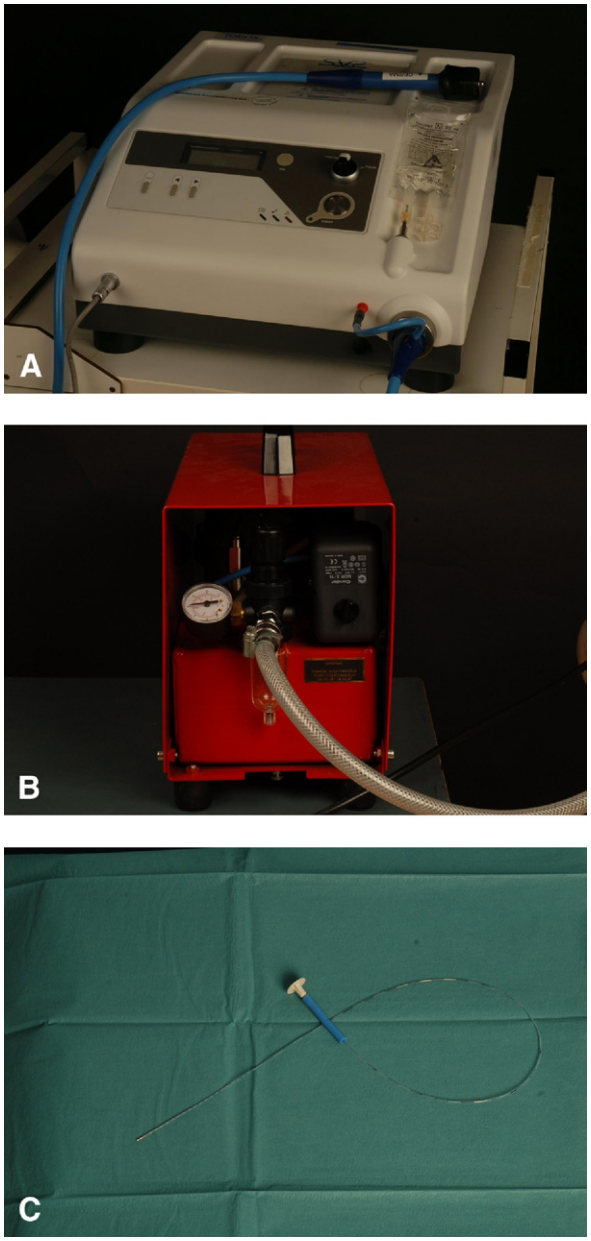


**Fig 1.** Photographs show **(A)** the Steam Vein Sclerosis device, **(B)** the steam generator, and **(C)** the steam catheter.

system consists of a steam generator and a handpiece that injects micropulses of steam into a catheter that delivers the steam into the vein to be treated (Fig 1). A more detailed description of the steam ablation procedure is given in "Procedures" of the pilot study in patients. The procedure in sheep was very similar to the procedure in humans.

### Experiments in sheep

The sheep used in this study received care in compliance with the FDA Good Laboratory Practice (GLP) regulations 21 CFR 58 (revised April 1, 2005).

The experiments in sheep consisted of two parts. The first was a safety assessment during steam ablation by caval vein blood temperature measurement, subcutaneous temperature measurement, and monitoring of hemodynamic parameters. The second part consisted of measurements of the vein diameter by US imaging for 3 months after the steam treatment and microscopic investigation of treated veins after euthanasia of the sheep.

**Steam ablation procedure.** The steam ablation in six sheep was performed under general and tumescent (sterile saline with 1% lidocaine) anesthesia. To measure perivenous temperature, sensors were inserted under the skin close to the saphenous vein. Sensors were placed inside two veins to measure initial and final intravascular temperatures. During treatment, electrocardiography, arterial blood pressure, heart rate, and oxygen saturation were monitored. In one sheep, a temperature-monitoring catheter was inserted into the contralateral saphenous vein and threaded up into the inferior caval vein to measure blood temperature during steam ablation.

A US examination was performed to measure the vein diameter before, immediately after, and at 1 and 3 months. Macroscopic examination was performed immediately, >20 days after, or 3 months after the treatment.

On four of the six sheep undergoing the steam ablation procedure, we performed US examination to measure diameter shrinkage; two of these four sheep were used for intravascular temperature measurement, two were used for perivenous temperature measurement, and all four sheep were used for macroscopic examination. These four sheep were euthanized 3 months after steam ablation. Two other sheep (2462 and 41083) were used for macroscopic examination (one with excision of a small part of the vein immediately after treatment) for perivenous temperature measurements and one also for caval vein temperature measurement. These two sheep were euthanized 20 days after treatment. Hemodynamic parameters were measured in all six sheep. To test the validity of the animal study, two veins from two of the sheep were treated with RFA in a standard fashion.

### Pilot study

**Patients.** The pilot study included 20 veins of 19 consecutive patients presenting at our Department of Dermatology with primary insufficiency of the great saphenous vein (GSV) or short saphenous vein (SSV) with typical complaints such as tired legs and heaviness, defined by reflux time >0.5 seconds and a vein diameter >5 mm. The exclusion criteria for patients included age <18 years, acute deep or superficial vein thrombosis, agenesis of deep vein system, vascular malformations or syndromes, occlusive postthrombotic syndrome, pregnancy, immobility, allergy to lidocaine, and arterial insufficiency (ankle-brachial index <0.9). In the Netherlands, the introduction of a new medical device with a CE registration number, such as the SVS system, does not require permission of the medical ethical committee.

**Procedure.** The procedure of steam ablation is very similar to EVLA. Steam ablation was performed with the

**Table I.** Steam ablation in sheep, treatment parameters

| *Sheep No.* | *Limb* | *Puffs/cm* | *Withdrawal (cm)* | *Total puffs (No.)* | *Total energy (J)* | *Energy (J/cm)* |
|---|---|---|---|---|---|---|
| | | | | | *Mean (SD)* | *Mean (SD)* |
| 2462 | Right | 3 | 1 | 42 | 1592 (67) | 114 (4.8) |
| 2462 | Left | 1 | 1 | 24 | 910 (38) | 38 (1.6) |
| 41083 | Right | 3 | 1 | 39 | 1474 (35) | 59 (1.4) |
| 41083 | Left | 2 | 1 | 42 | 1588 (38) | 76 (1.8) |

*SD,* Standard deviation.

patient under local tumescent anesthesia in an outpatient setting. The vein was punctured with a 16-gauge infusion needle under US guidance. The insufficient GSV was mostly entered at or just above knee level because access is easy at that site and the risk of nerve injury is small. The SSV was entered halfway or at the distal third part of the calf, depending on vein diameter. After puncturing the vein, the steam catheter (1.2-mm diameter) was passed through the hollow needle into the vein until positioned 3 cm below the junction. The most pivotal step in the procedure is positioning the echo-dense tip of the sheath approximately 3 cm distally from the junction under longitudinal US visualization.

About 150 to 300 mL (depending on the length of vein treated) of tumescent anesthesia (5 mL epinephrine [5 mL bicarbonate] and 35 mL lidocaine 1% diluted in 500 mL saline solution) was administered into the perivenous space under US guidance using a mechanical infusion pump. Tumescent anesthesia is necessary because it reduces pain, cools perivenous tissue, and decreases the venous diameter.

After activation, the catheter releases small "puffs" of steam, and the catheter was pulled back stepwise. With the first activation 3 cm below the (saphenofemoral or saphenopopliteal) junction, four puffs of steam were administered, meanwhile with manual pressure on the junction. Two puffs of steam were administered at 1-cm intervals. During the first 4 cm of treatment, manual compression on the junction was still applied. After the first 12 treatments, we reduced the amount of administered energy to one puff per further cm in patients with a vein diameter <8 mm. This was because a few patients reported the sensation of feeling heat during the treatment and because good results with using less energy in smaller veins was observed during the evolution of the method.

A physicist calculated that approximately 2258 J is released when 1 g of steam condenses. In EVLA, it is considered consensus to apply about 50 to 60 J/cm. To occlude 30 cm of vein with steam ablation, theoretically, 1 to 1.5 mL of water is needed. In practice, 2 to 5 mL of water is likely to be required, because not all steam condenses at the vein wall.

The steam is produced by means of piston pressing a fixed amount of water (76 μL = diameter piston × stroke) through a heated element located just before the catheter. By keeping the lumen diameters very small and the exit holes even smaller, pressure is maintained and loss of energy is limited. The volume of the steam depends on the pressure and temperature. As the energy is transferred to the vein, the steam cools and condenses to the same volume of water used to produce the steam. The steam starts to cool and condense when it leaves the catheter due to the drop in pressure and the exchange of energy with the surroundings. This process is dynamic. The theoretic amount of energy of one pulse of steam is 174 J. The measured amount released at the tip of the catheter is 60 J per pulse. However, additional dose-finding studies are warranted.

After the procedure, patients were advised to wear thigh-length medical elastic compression stockings (pressure range, 25-35 mm Hg) for 1 week and to mobilize immediately after the treatment.

**Statistical analysis.** Variables were presented in means with standard deviation (SD) if distributed parametrically, or as median with the 25th and 75th percentile value (interquartile range [IQR]) if distributed nonparametrically. We compared the scores of the EuroQol quality-of-life questionnaire (EQ-5D) index and visual analog scale (VAS),[5] Aberdeen Varicose Vein Questionnaire (AVVQ),[6] and Venous Clinical Severity Score (VCSS)[7] before and 3 months after therapy using the Wilcoxon signed-rank test. We performed statistical analysis with SPSS 15.0 software (SPSS Inc, Chicago, Ill) and assigned significance at $P < .05$ (two-sided $P$).

## RESULTS

### Experiments in sheep

**Safety.** The treatment parameters for four treated limbs are summarized in Table I. No temperature rise was observed at the level of the vena cava inferior in sheep 41083. In sheep 2462, a temperature rise from 30° to 59°C was observed with the subcutaneous thermocouple in the left limb and from 30° to 32°C in the right limb. The temperature rise was from 30° to 38°C in the right and left limb of sheep 41083. Noninvasive arterial blood pressure, heart rate and oxygen saturation remained stable during treatment in all sheep. Only a transient lower oxygen saturation was observed in the right limb of sheep 41083. The intravascular temperature increased at the end of the procedure in one of two veins from 36.4° to 40°C.

**Morphologic changes in vein diameter.** Before treatment, the diameters of the veins varied between 0.28 and 0.35 cm. US examination demonstrated that all veins were occluded and that the diameter of each vein decreased directly after the steam ablation. The diameters continued

**Table II.** Morphologic changes measured by ultrasound examination

| | | | *Vein diameter, cm* | | | | |
|---|---|---|---|---|---|---|---|
| *Sheep No.* | *Limb* | *Energy (J/cm)* | *Before Tx* | *After Tx* | *At 1 mon* | *At 3 mon* | *Difference after 3 mon* |
| 2872 | Right | 40 | 0.28 | 0.25 | 0.17 | 0.15 | 0.13 |
| 3347 | Left | 80 | 0.32 | 0.28 | 0.28 | 0.18 | 0.14 |
| 2343 | Right | 40 | 0.34 | 0.29 | 0.21 | 0.22 | 0.12 |
| 2343 | Left | 80 | 0.35 | 0.27 | 0.23 | 0.15 | 0.20 |
| 1481 | Right | 80 | 0.31 | 0.28 | 0.18 | 0.18 | 0.13 |
| 1481 | Left | 40 | 0.33 | 0.25 | 0.20 | 0.19 | 0.14 |
| Mean (SD) | | NA | 0.32 (0.18) | 0.27 (0.13) | 0.21 (0.29) | 0.18 (0.19) | 0.14 (0.19) |

*NA,* Not applicable; *SD,* standard deviation; *Tx,* treatment.

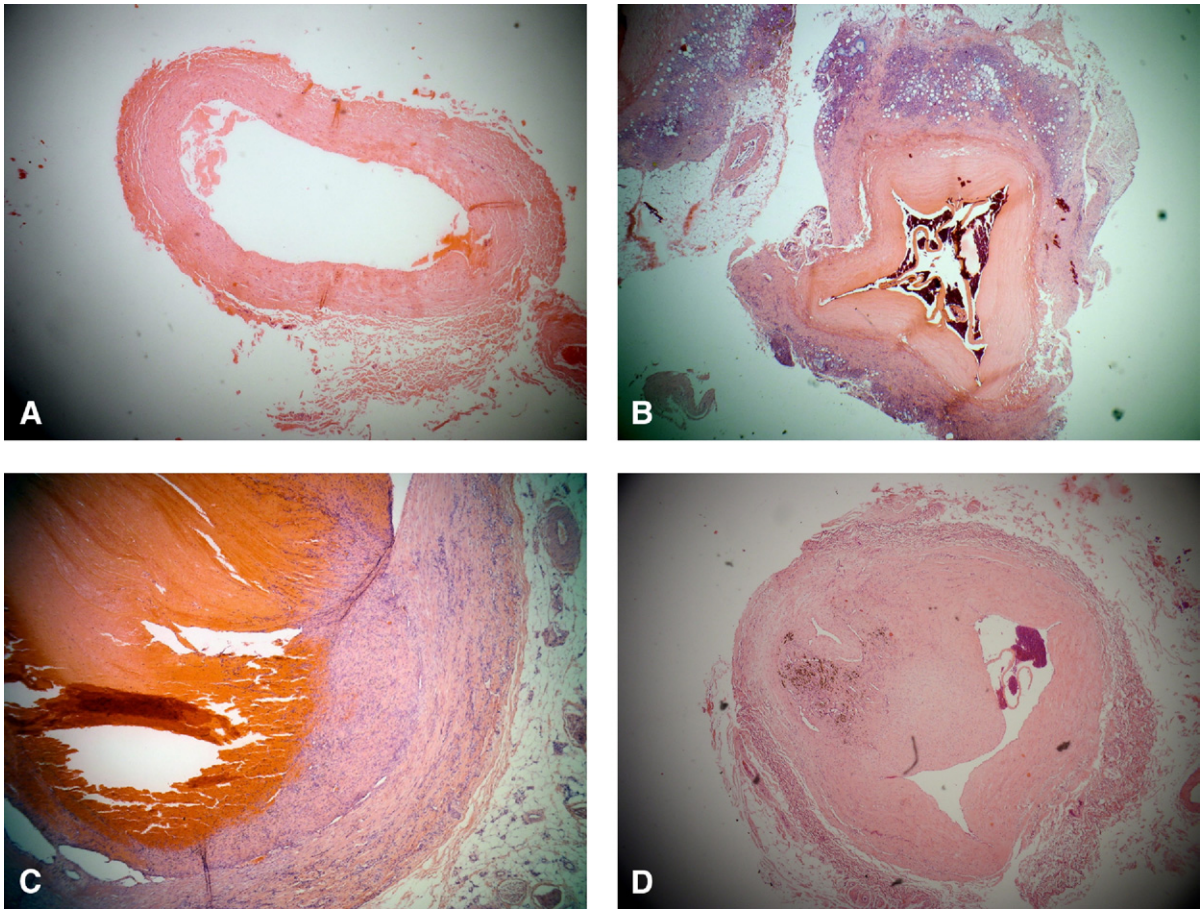


**Fig 2.** Photomicrographs show a vein **(A)** immediately after treatment with steam ablation and **(B)** at 20 days after treatment with steam ablation (both hematoxylin-eosin stain, original magnification ×40). **C,** Detail (hematoxylin-eosin stain, original magnification ×200). **D,** Photomicrograph shows a vein 3 months after treatment with steam ablation (hematoxylin-eosin stain, original magnification ×40).

to decrease over time, with a mean decrease in initial diameter of 56% (SD, 4.8%) after 3 months (Table II).

**Microscopic examination.** Microscopic examination of veins immediately after the steam ablation showed disappearance of the endothelial layer, with negative marking for factor VIII and a few cleavage zones in the media (Fig 2, *A*) Microscopic examination of treated veins that were removed 20 days after the steam ablation showed endothelial destruction, fibrotic thrombosis with inflammatory reaction of the media, major alterations of elastic and collagen fibers in the media, and lesions in the adventitia with liponecrosis and lipogranuloma (Fig 2, *B and C*) Locally, the inflammatory reaction extended to the adventitia. Three months after the steam ablation, microscopic examination showed (major) thickening of the vein wall with fibrosis and inflammation, destruction of endothelium, al-

**Table III.** Patient characteristics

| *Variable* | *No. or Mean (SD)* |
|---|---|
| Patients | 19 |
| Legs | 20 |
| GSV | 17 |
| SSV | 3 |
| Age, y | 53 (15) |
| Sex | |
| Female | 12 |
| Male | 7 |
| CEAP | |
| $C_2$ | 11 |
| $C_3$ | 2 |
| $C_4$ | 4 |
| $C_5$ | 2 |
| $C_6$ | 0 |
| Treated length, cm | 25 (7) |
| Pulses, No. | 50 (19) |

*GSV,* Great saphenous vein; *SD,* standard deviation; *SSV,* small saphenous vein.

terations of elastic and collagen fibers, numerous pigmented histiocytes, a significant reduction of the lumen, and capillary neovessels. There were also focal areas in which the endothelium was preserved (Fig 2, *D*). The observed histologic changes were similar to those found after treatment with RFA.

### Pilot study

**Study population.** The study comprised 19 patients (7 women) who were a mean age of 53 years (Table III). Of the 20 veins treated, 17 were GSV and 3 were SSV. More than half of the treated patients were considered clinical class 2 of the CEAP classification.

**Outcomes.** The mean treated length of the veins was 25 cm, and an average of 50 pulses of steam were administered per treated vein (Table III). All treated veins were occluded on US examination at 1 week. At 3 months, 1 of the 20 treated varicose veins showed a small segment of several centimeters with minimal blood flow. At 6 months, flow was observed on US examination in 7 of 20 treated saphenous veins, but this was a small string (never filling the entire venous diameter) over a tract of <10 cm. In only two of seven cases did the strings of flow show minimal reflux. At the 1-week follow-up, there were no cases of deep vein thrombosis, skin burns, nerve injury, infections, or hyperpigmentation. One patient had transient superficial phlebitis distally from the treated part, and nine patients had some ecchymosis only at the puncture site, but not along the treated vein. No complications were reported by the patients or were detected with US at 3 and 6 months of follow-up.

The median VCSS decreased significantly from 5.0 (IQR 3.3, 9.3) to 2.5 (IQR 1.0, 5.0) 3 months after the treatment ($P < .001$; Fig 3). Of the three patients in whom the VCSS remained identical, the absolute scores were 2, 10, and 14. The AVVQ improved significantly from 12.6 (IQR 6.9, 25.1) to 9.8 (IQR 2.1, 17.9; $P = .027$). Although the EQ-5D index improved 3 months after the

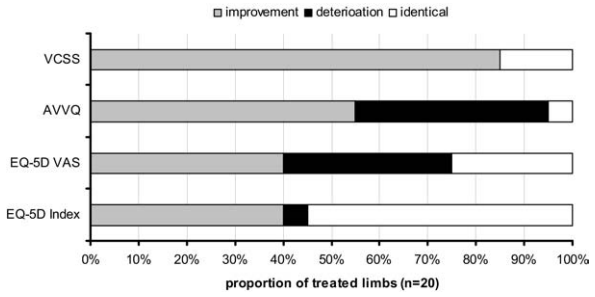


**Fig 3.** The positive, neutral, and negative impact of steam ablation is shown on the Venous Clinical Severity Score *(VCSS),* Aberdeen Varicose Vein Questionnaire *(AVVQ)*, and the EuroQol quality-of-life questionnaire (*EQ-5D*) index and visual analog scale (VAS), four measures of clinical and health-related quality-of-life.

treatment in eight patients and deteriorated in one, the difference was not significant ($P = .11$). The VAS of the EQ-5D did not change considerably after steam ablation (median remained 80 of 100, $P = .56$). Median satisfaction of the treatment was 9.25 (IQR 8.6, 10.0) and median maximal pain after steam ablation was 1 (IQR 0, 2) on a 10-point VAS. Four patients used four to six analgesics (500 mg paracetamol or a nonsteroidal anti-inflammatory drug) daily 1 or 2 days after the treatment.

## DISCUSSION

In this study, we have described the first results of a new technique to ablate varicose veins using high-temperature steam, which appears to be safe, effective, and appreciated by patients.

In sheep veins treated with steam ablation, fibrosis and destruction of the vein was confirmed by histology, and ongoing fibrotic contraction was confirmed by shrinking of vein diameter on US imaging. The similar histologic changes found after heating using the RFA technique show that our study design was valid and very much in line with previous observations.[8]

In the 20 veins treated in the patients, 13 were completely occluded and 7 showed minor recanalization on US examination at 6 months of follow-up. Although the number of partial recanalizations increased from 1 to 7 between 3 and 6 months of follow-up, the clinical relevance of this finding is unclear. The observed flow on US examination was limited and may reflect a process of venous remodelling as is observed after RFA. This deterioration emphasizes the need for clinical dose-finding studies in SVS (ie, number of steam pulses/cm).

Many observational studies—but few randomized controlled trials—have shown the high efficacy of EVLA, and a recent meta-analysis of all available data after an adjustment for follow-up demonstrated that EVLA was more effective than stripping, RFA, and US-guided foam sclerotherapy.[2] Only two publications have reported radiofrequency-powered segmental thermal ablation, which has a heating element of 7 cm. The first was a case series that showed occlusion rates of 99% after 6 months of follow-up.[9] The

second was a randomized controlled trial that compared EVLA with radiofrequency-powered segmental ablation measuring posttreatment recovery and quality-of-life parameters, in which the authors concluded that the radiofrequency-powered segmental ablation was superior.[10] Because thermal endovenous treatments are very effective, the challenge is now to search for the one that is the safest, cheapest, and most appreciated by patients and physicians (optimal risk-benefit ratio).

Our second finding concerned the safety of steam ablation, which was demonstrated by stable hemodynamic parameters and low perivenous temperatures in the sheep during steam ablation, and neither did the 19 patients have any major complications, such as DVT or nerve injury. Two other features that might be advantageous compared with EVLA are that steam ablation is performed with a very small volume of sterile water (approximately 2 mL per treated vein) and that the temperature is relatively constant, with a maximum of 120°C. Carbonized blood is released during EVLA, and the temperature is very variable, rising to 600° to 1000°C, and sometimes even melting the fiber tip.[11] The steam catheter, in contrast, is introduced directly through the puncturing needle, without the need for a guidewire or sheath, resulting in an easier and safer procedure. There is less risk of device-related complications, such as the retention of a guidewire inside the body, which has been reported in EVLA.[12-13]

The patient-reported outcomes suggest that steam ablation was very well tolerated. The pain scores were low, and patients were very satisfied with the treatment. The clinical disease severity, as measured by the VCSS, improved significantly, and the AVVQ disease-specific questionnaire showed a significant improvement after steam ablation. Whether these patient-reported outcomes are better than with EVLA and RFA has to be assessed in a comparative study.

An advantage of the steam-ablation procedure is that the catheter is minute and very flexible. The diameter of the SVS steam catheter (1.2 mm) is almost 50% smaller than that of the segmental RFA (2.33 mm). The flexibility may facilitate placement of the catheter into branches, tortuous vessels, and perforator veins, which are sometimes difficult to access with the more rigid catheters used in RFA and the stiff glass fibers used in EVLA. The steam is released from two small areas at the tip of the catheter, allowing treatment of any length of vein, which is not possible with the segmental RFA with a 7-cm-long stiff heating tip. The steam is released under pressure and, therefore, disperses over a distance of at least 2 cm. This may be of additional benefit in the treatment of short perforator veins and short segments of meandering veins.

The limitations of this study were the limited number of treated limbs and the lack of comparison with established methods. The main objective was, however, not to prove superiority over another method but to show that the steam ablation of the saphenous veins is feasible to perform safely in animals and humans with satisfactory short-term results. Larger comparative studies are needed to compare the long-term efficacy and the risk-benefit ratio of steam ablation with those of existing endovenous techniques.

## CONCLUSION

Steam ablation of the saphenous vein using the SVS is a novel method of endovenous thermal ablation. It appears to be safe, effective, and highly appreciated by patients. It may potentially have advantages over currently available thermal therapies.

## AUTHOR CONTRIBUTIONS

Conception and design: RB, RM, MN, TN
Analysis and interpretation: RB
Data collection: RB, RM
Writing the article: RB, TN
Critical revision of the article: RB, RM, MN, TN
Final approval of the article: RB, RM, MN, TN
Statistical analysis: TN
Obtained funding: MN
Overall responsibility: TN

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